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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/419,262

Applicant(s)

French, et al.

Examiner

Mary B. Tung

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Mar 19, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above, claim(s) 3 and 21-38 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 2, and 4-20 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s) _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6

20) ☐ Other

DETAILED ACTION

Priority

1. Acknowledgment is made of Applicant's claim for foreign priority. It is noted, however, that a certified copy of the German application as required by 35 U.S.C. 119(b), has not been received.

Election/Restriction

2. Applicant's election, without traverse, of Group I, claims 1-20 in the paper filed March 19, 2001, Paper No. 8 is acknowledged.

3. Groups II-V, claims 21-38 are withdrawn from further consideration by the Examiner, 37 C.F.R. 1.142(b), as being drawn to non-elected inventions.

4. Applicant has further elected in Paper No. 8, the species of GVHD. Claims 1, 2 and 4-20 are readable on the elected species. Claim 2 is patentably distinct and are accordingly held to be withdrawn from further consideration under 37 C.F.R. 1.142(b).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Information Disclosure Statement

6. The information disclosure statement filed fails to comply with 37 C.F.R. 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The references lines through on the PTO Form 1449, filed July 6, 2000, Paper No. 6 were considered to the extent possible by the Examiner. However, the International Search Report, lined through on the 1449 form is not proper art and thus is not suitable for printing on the front of the patent, if the instant application passes to issue. All other references were fully considered.

Claim Rejections - 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the Applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the Applicant for patent.

- 8. Claims 1, 2, 4 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hattori, et al. (*Blood* 91(11):4051-4055, June 1, 1998).
- 9. Hattori, et al. teaches a method of treating a subject having GVHD, using a composition comprising antibodies to Fas ligand. (see page 4051, col. 2 and page 4052, col. 2). Therefore, the reference teachings anticipate the claimed invention.

Claim Rejections - 35 U.S.C. § 103

- 10. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).
- 12. Claims 1 and 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hattori, et al. (*Blood* 91(11):4051-4055, June 1, 1998).
- 13. Hattori, et al. has been discussed, *supra*. Hattori also teaches wherein the composition is administered at a dose of 0.1 g/kg (a mouse weighs an average of 20 g, therefore: 2 mg = 2×10^3 g; 20 mg = 20×10^{-3} kg. 2×10^3 g / 20×10^{-3} kg = 0.1 g/kg), over a period of 7 days (see page 4051, col. 2 and page 4052, col. 2), as recited in claims 9, 11, 16 and 19. Hattori also teaches the use of anti-Fas ligand antibodies in humans (see page 4054,

col. 2, last paragraph), as recited in claim 15. The claimed invention differs from the reference teaching only by the recitation of the composition being administered as an intravenous immunoglobulin mixture, as recited in claims 5 and 14, and wherein the immunoglobulin mixture is administered at a dose of at least 0.75 g/kg/day. One of ordinary skill in the art at the time the invention was made would have been motivated to substitute an intravenous solution in place of an IP administration, as the technical skill and comfort of an IV administration are superior using an IV administration. Additionally, the higher dosages recited in claims 12 and 20 would be well within routine dosage trials. The concentration of the anti-Fas antibody, recited in claim 17 is irrelevant, since the concentration would be adjusted to the final concentration required for administration. The inhibition percentages recited in claims 7 and 8 would be characteristics of the administration of the composition, absent evidence to the contrary. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

14. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.
15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm and on alternating Mondays. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

May 25, 2001
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640

Mary Tung
MARY BETH TUNG, Ph.D.
PATENT EXAMINER